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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,952

05/04/2005

Toshikazu Koyama

1349.45033X00

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20457 7590 03/04/2008  
ANTONELLI, TERRY, STOUT & KRAUS, LLP  
1300 NORTH SEVENTEENTH STREET  
SUITE 1800  
ARLINGTON, VA 22209-3873

EXAMINER

UNDERDAHL, THANE E

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

03/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,952	<b>Applicant(s)</b> KOYAMA ET AL.	
	<b>Examiner</b> THANE UNDERDAHL	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-25 is/are pending in the application.
- 4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-12 and 23-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This Office Action is in response to the Applicant's reply received 12/10/07.

Claims 1, 3-25 are pending. Claims 13-22 are withdrawn. Claim 2 is cancelled.

Claims 1 and 5 have been amended. Claims 23-25 are new.

#### **Response to Applicant's Arguments— 35 U.S.C § 112**

In the response submitted by the Applicant the 35 U.S.C § 112 rejection of claim 5-9 is withdrawn in light of the Applicant's amendment.

#### **Response to Applicant's Arguments— 35 U.S.C § 102**

In the response submitted by the Applicant, the 35 U.S.C § 102 (b) rejection of claims 1, 3-5 and 7-9 over Shibahara et al. (U.S. Patent # 5753223) were considered but not found persuasive. Also the prior art of Shibahara et al. also anticipates the new claims 23-25.

The Applicant argues primarily that Shibahara et al. teaches the addition of the enzyme (bioactive material) in a core material made of sugar and not in the coating. More specifically, the Applicant argues that their invention comprises a core material that is coated with a hardening oil. This hardening oil has enzymes suspended in it. While the Examiner recognizes the subtleties of this argument the claims as written do not necessarily reflect such limitations. As read by the Examiner, claim 1 is to a granular composition comprising A) a core material of saccharides such as granulated sugar or lactose and B) A layer of hardening oil that contains a bioactive ingredient such as an enzyme that coats the core of A. The Examiner understands that the enzyme is

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limited to be in the hardening oil coating. However the open language of "comprising" in the composition does not limit that additional coats may be present.

This is what is taught in Example 8 cited by the Examiner in the previous Office Action. Specifically, Shibahara et al. dissolves the enzyme pancreatin into a hardened beef tallow (col 9, lines 33-35). This "resultant coating composition" was coated onto the cores of the composition (col 9, lines 35-45). Shibahara et al. then coats the particles again with hardened beef tallow. Furthermore the Examiner would like to point out that Control Example 1 (col 9, line 52) also coats core particles with enzymes suspended in hardening oil and makes no mention of an additional topcoat. While the Examiner understands that Shibahara et al. expressly teaches "the outermost surface portion contains substantially no enzyme/or enzyme activator" (col 4, lines 58-59). However they do teach that this could include situations where the outer surface contains "an extremely small amount of enzyme" or enzyme is in the outermost surface with an inhibitor (col 4, lines 60-67). Therefore Shibahara et al. does teach situations where the enzyme suspended in the hardened oil coating is covering the core.

Also, it is acknowledged that the prior art of Shibahara et al. as a whole must suggest the desirability of the invention, but a finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggest that the combination claimed is the preferred, or most desirable combination. The prior art's mere disclosure of more than one alternative does not constitute a teaching away from the claimed invention because such

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disclosure does not criticize, discredit, or otherwise discourage the solution claimed in the patent application. See *In re Fulton*, 391 F.3d 1195, 73 USPQ2d 1411 (2004).

Therefore the rejection stands and is repeated below and is amended to include new claims 23-25.

Claims 1, 3-5, 7-9 and 23-25 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shibahara et al. (U.S. Patent # 5753223) with support from Answers.com.

These claims are drawn to a granular composition that has two parts: a core made of saccharides and a coating that is made of hardened oil and a bioactive ingredient.

The core comprises granulated sugar or lactose. The hardened oil is further limited to palm oil. The bioactive ingredient is limited to an enzyme from the group consisting of a cellulase, amylase, protease, and lipase. Claims 7-9 are Product by Process claims that limit the origin of the enzymes. Product by Process claims are not limited by the origin of the enzymes, only the structure implied by the enzymes to the composition (M.P.E.P. § 2113). As such, these methods of preparation do not impart a functional relationship to the granular composition and are not further limiting and unless the applicant provides evidence to the contrary that the origin of the enzyme is indeed a necessary limitation, the claim will read on any of the selected enzymes regardless of origin. Claims 23-25 further limit that the bioactive ingredient is in the hardening coating and not in the core material.

Shibahara et al. teach a granular composition comprising a core material coated with a hardened oil and bioactive ingredient such as enzyme or pancreatin (Shibahara, Abstract and Example 8). Example 8 and Control Example 1 explicitly show that the enzymes exclusively in the coating and not in the core material. The core material are granulated sugars such as sucrose, glucose and starch (Shibahara, col 3, lines 30-35). The hardened oil can be palm oil (Shibahara, col 4, lines 1-5). The enzymes in the coating can be lipase (Shibahara, col 4, lines 10-15) or a mixture of enzymes (Shibahara, col 4, 20-25) such as pancreatin (Shibahara, Example 8) which inherently contains, amylase, lipase and the protease trypsin as supported by Answers.com (Definition: Pancreatin).

Therefore the reference anticipates claims 1, 3-5, 7-9 and new claims 23-25.

### **Response to Applicant's Arguments— 35 U.S.C § 103**

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 1-5, 7-9 and 12 over Shibahara et al. were considered but not found persuasive. The same conclusion was reach in the 35 U.S.C § 103 (a) of Shibahara et al. in view of Nishimura et al. (U.S. Patent # 5571527) to obviate claims 1-9 and 12 and Shibahara et al. in view of Ludwig et al. (U.S. Patent # 4293539).

The Applicant argues that these two references applied do not overcome the perceived insufficiencies of Shibahara et al. This insufficiency being that Shibahara et al. does not teach that the saccharide cores are coated with a hardening oil with

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suspended enzyme. However as reiterated in the rejection above, indeed Shibahara et al. does teach such a composition and without further argument against the combination of these references the respective rejections stand and are repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 7-9, 12 and 23-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Shibahara et al. (U.S. Patent # 5753223) as applied to claims 1, 3-5, 7-9 and new claims 23-25 above and further view of arguments below.

The description and rejection of claims 1, 3-5, 7-9 and new claims 23-25 are listed in the 35 U.S.C § 102(b) rejection above. Claim 12 limits that the bioactive agent is 0.1 to 15% by weight in the coating.

While Shibahara et al. teaches that bioactive ingredients such as enzymes are indeed in the coating and they state concerning the concentration of the coating that "The amount of enzyme used is not limited" (Shibahara, col 4, lines 20-25), Shibahara et al. does not specifically teach the limitations of claim 12. However, M.P.E.P. § 2144.05 II states:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Absent any teaching of criticality by the applicant concerning the amounts listed in claim 12 for the concentrations of bioactive ingredients, it would be *prima facie* obvious that

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one of ordinary skill in the art would recognize that the concentrations are result effective variables whose ratio and concentration are a matter of routine optimization.

Therefore the references listed above renders obvious claims 1, 3-5, 7-9, 12 and 23-25.

Claims 1, 3-9, 12 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibahara et al. as applied to claims 1, 3-5, 7-9 and new claims 23-25 above, and further in view of Nishimura et al. (U.S. Patent # 5571527).

The description and rejection of claims 1, 3-5, 7-9, 12 and 23-25 are listed in the 35 U.S.C § 103(a) rejection above. Claim 6 limits that the enzyme is cellulase. While Shibahara et al. does not explicitly teach the addition of cellulase to their coating they do teach that their enzymes in the coating layer are meant to “enhance(s) the effects of the digestive enzymes secreted by the ruminant ...as well as dissolution of the biologically active substance” (Shibahara et al., col 5, lines 25-30). Furthermore the granulated saccharide core of Shibahara et al. contains components such as starch, glucose, sucrose (Shibahara, col 3, lines 30-35) and carboxymethylcellulose (Shibahara Example 6). Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Nishimura et al. who teach an another composition that contains a coating. Nishimura et al. teach the addition of cellulase as well as lipase and amylase to their composition (Nishimura, col 6, lines 1-5) to assist in digestion (Nishimura et al. col 1, lines 30-35). One of ordinary skill in the art would recognize that ruminant animals have cellulase in their digestive tracts to process



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high cellulose foods such as grass. It would have been obvious to someone skilled in the art to add cellulase to the coating in the invention of Shibahara et al. Since Shibahara et al. provides motivation by stating that the enzymes in the coating layer are meant to (A) “enhance(s) the effects of the digestive enzymes secreted by the ruminant” as well as assist in the (B) “dissolution of the biologically active substance” (Shibahara et al., col 5, lines 25-30) it would have been obvious to someone skilled in the art that the addition of cellulase accomplishes both of these goals. First in object (A) adding more cellulase to the digestive track will enhance the digestibility of high cellulose food in the ruminant. Also (B) will be achieved since the formulations of Shibahara et al. include cellulose derivatives that would be broken down by the cellulase and provide added nutrient to the ruminant animal. The reasonable expectation of success is provided by Nishimura et al. who teach a composition for ruminants where cellulase is added to enhance digestion. Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 1, 3-9, 12 and 23-25 are not allowable.

Claims 1, 3-5, 7-12 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibahara et al. as applied to claims 1, 3-5, 7-9, 12 and 23-25 above, and further in view of Ludwig et al. (U.S. Patent # 4293539).

The description and rejection of claims 1, 3-5, 7-9, 12 and 23-25 are listed in the 35 U.S.C § 103(a) rejection above. Claims 10 and 11 are limit that the bioactive ingredient in the coating is the antibiotic, colistin.

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Shibahara et al. teach the addition of antibiotics to their composition for ruminant animals (Shibahara, col 3, lines 40-45) but does not teach that they are in the coating. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Ludwig et al. They teach a composition that contains many of the similar coating ingredients such as beeswax, gelatin, cocoa butter and alginic acid with similar properties (Ludwig, col 5, lines 48-55) of those of Shibahara et al. including vegetable and animal oils that also harden or gel. One of ordinary skill in the art would recognize that both compositions could be used to coat the cores of the invention Shibahara et al. since these coating components do have similar properties to gel. The composition of Ludwig et al. is also to act as a supplement to treat ruminant animals. In particular Ludwig et al. teach that their composition includes the antibiotic colistin (Ludwig et al. col 4, lines 35-40). It would have been obvious to someone skilled in the art to combine the teachings of Shibahara et al. with those of Ludwig et al. and add the antibiotic colistin to the hardened oil coating formulation of Shibahara et al. The motivation comes from Ludwig et al. who successfully treats ruminants with antibiotics using supplement polymer formulations that use vegetable oils and gelatin that have similar properties such as gelling as those used by Shibahara et al. The reasonable expectation of success comes from Ludwig et al. who successfully treat the ruminants with their gel-like formulations.

Therefore the references listed above renders obvious claims 1, 3-5, 7-12 and 23-25.

#### **New Rejections Necessitated by Amendment**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 contains the limitation that “the core material is free of bioactive ingredient”. However, claim 1 does not specifically define the bioactive ingredient and the broad use of the term of bioactive material can include saccharides. This limitation of claim 25 contradicts claim 1 that specifically limits that saccharides must be in the core material. Clarification is required.

In summary no claims, as written, are allowed for this application.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure**, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

#### CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/  
Primary Examiner, Art Unit 1651

Thane Underdahl  
Art Unit 1651

Leon B. Lankford Jr  
Primary Examiner  
Art Unit 1651